# PHASEOUT OF DONATED CONTRACEPTIVES: LESSONS LEARNED FROM THE CASE OF CEPEO

Ву

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The PROFIT (Promoting Financial Investments and Transfers) Project seeks to mobilize the resources of the commercial sector to expand and improve the delivery of family planning services in selected developing countries. The PROFIT Project is a consortium of five firms, led by the international management consulting firm of Deloitte Touche Tohmatsu and including the Boston University Center for International Health, Multinational Strategies, Inc., Development Associates, Inc., and Family Health International.

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# **ACRONYMS**

BEMFAM IPPF affiliate (largest family planning NGO in Brazil)

BMZE Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung

CEPARH leading family planning/maternal health institution in the Northeast

CEPEO Commodities Procurement Organization
CIDA Canadian International Development Agency

CPAIMC major reproductive health care NGO in Rio de Janeiro

CPR contraceptive prevalence rate
DKT International major donor of contraceptives
DHS Demographic and Health Surveys

EC European Commission FEI Finishing Enterprises

HIV/AIDS human immunodeficiency virus/acquired immunodeficiency syndrome

HMOs health maintenance organizations INT National Institute of Technology

IPPF International Planned Parenthood Federation

IUDs intrauterine devices

KfW Kreditanstalt für Wiederaufbau MSI Marie Stopes International

MOH Ministry of Health

MWRA married women of reproductive age NGOs nongovernmental organizations

ODA Overseas Development Administration

Pathfinder International USAID cooperating agency

PROFIT Promoting Financial Investments and Transfers SIDA Swedish International Development Agency

SOMARC III project social marketing project funded by USAID's Office of Population and

managed by The Futures Group

STDs sexually transmitted diseases

Summa Foundation U.S.-based nonprofit company created by PROFIT in 1992

UNFPA United Nations Population Fund

USAID U.S. Agency for International Development

WHO World Health Organization WRA women of reproductive age

# INTRODUCTION

# 1.

For several decades international donors have recognized the need to reduce population growth to sustainable levels by meeting the reproductive health needs of families. USAID, for example, established a global population program in 1965 and by 1995 was committing \$983 million to such programs. Contraceptive commodities donated by USAID and others have been a major component of this assistance.

Resources to support international population programs are decreasing, however, even as demand for contraceptive products continues to grow. Donors are finding it necessary to phase out support of population programs in those countries that have achieved a relatively high level of contraceptive prevalence. Because phasing out often means an end to donated contraceptives, donors need to be concerned with minimizing the negative impact of withdrawing support and ensuring a sustainable source of affordable contraceptives for the poor families they have served.

USAID found itself in such a situation in Brazil. Because of declining USAID funding in general and Brazil's advances in contraceptive prevalence, in 1991 USAID resolved to phase out its population program in the country by 2000. This paper describes how USAID's phaseout strategy in Brazil was determined; how CEPEO (Commodities Procurement Organization), the for-profit company that was selected as the best phaseout strategy, was created; and how CEPEO was implemented and operated. Finally, to assist others in phaseouts of international family planning programs, the paper outlines the steps that USAID learned were essential during its experience in creating, running, and phasing out CEPEO.

# **DETERMINING POTENTIAL PHASEOUT STRATEGIES**

# 2.

Brazil, an advanced developing country, has the eighth largest economy in the world and the fifth largest population (approximately 150 million). However, Brazil also has one of the most unequal distributions of income, with significant differences in socioeconomic indicators by region and social class. The Northeast region is poorest and has 20 percent of the population.

Major population issues faced by USAID in Brazil included:

- # A high contraceptive prevalence rate (CPR) (76.7 percent) but a poor method mix (female sterilization 40 percent; pills 21 percent; condoms 4.4 percent; all other methods less than 4 percent) (DHS 1996). (See Appendix A.)
- # Dominance of female sterilization. Most sterilizations (70 percent) were performed in public institutions through the public health system, normally following a cesarean birth.
- Wide availability of pills without a prescription in retail pharmacies (where 88 percent of users obtained them). This had led to misuse and thus to unplanned pregnancies. Most married women were familiar with oral contraceptives (79 percent had used them), but only 20 percent were current users.

  Absence of a public sector role in family planning on both policy and service delivery levels until very
- # Absence of a public sector role in family planning on both policy and service derivery levels that very recently. Tubal litigation was the primary way public sector doctors were able to assist poor women.

To address these issues, USAID supported programs to promote reproductive health policies, increase demand for modern reversible contraceptive methods, establish service delivery systems, train providers and managers, and donate contraceptives. USAID focused on the Northeast region and spent approximately \$50 million on such activities between 1988 and 1994. Among international agencies, USAID provided the majority (57 percent or \$4.9 million) of commodity donations from 1990 to 1993.

In order to ensure a successful program phase out, questions that USAID needed to answer included:

1) What goals should be achieved by the time the supply of donated contraceptives ends? 2) What are the characteristics of the contraceptive market? 3) What are the strategy options for maintaining a supply of affordable contraceptives to former recipients of commodity donations?

#### 2.1 GOALS TO BE ACHIEVED

An abrupt end to contraceptive donations in any country risks eroding progress in increasing couples' ability to plan their families. Thus in any phaseout strategy the primary goal is to ensure continued access to affordable contraceptives for the clients who have received free or low-cost contraceptives from public sector and nonprofit organizations supported by USAID.

In Brazil, additional, related goals for USAID were to:

- # Improve the quality of family planning programs by expanding the range of methods available, improving the use of methods, and increasing the information available about reproductive health
- # Ensure that viable service delivery systems were available in target areas when USAID assistance ended by working with states and the private sector to promote sustainability
- # Document the impact of USAID population assistance to Brazil through data collection and analysis at key points in program implementation.
- # Clarifying such additional goals up front is important so that alternative phaseout strategies can be judged appropriately and so that, once general goals have been defined, specific objectives can be set for each organization or sector.

#### 2.2 CONTRACEPTIVE MARKET CHARACTERISTICS

Analyses of data on the contraceptive market—the demand for and supply of contraceptives in the social and commercial sectors—is essential. These analyses assist in setting goals, in determining strategy options, and in implementing the strategy chosen. Analyses should be method specific: each contraceptive method can have very different supply, demand, and pricing conditions. Analysis should be ongoing and updated as new information becomes available.

Important components of any analysis are sociodemographic, donor supply, public sector, nongovernmental organization (NGO), commercial sector, and demand estimate data. Planners should collect as much data as possible within time and fiscal constraints even though the quality and amount of available data may be less than desired (especially commercial sector data, which is often proprietary).

# **"** Sociodemographic data

Collect and analyze information on contraceptive prevalence by method and region, socioeconomic characteristics of users of each method (age, marital status, education, ethnic group/religion), and sources of contraceptives (pharmacies, private doctors and clinics, government facilities, NGOs) by method. A valuable source for information on demand for and supply of contraceptives in a country are the Demographic and Health Surveys (DHS). Sources for data on income, which are important for evaluating the market's purchasing power, include national census data and the World Bank.

# **Donor supply data**

Collect and analyze information on the number of contraceptives supplied by each donor in the country over the past three to five years by type and recipient as well as on each donor's plans to provide donations of contraceptives over the next five years. These data are often available in printed documents and through interviews with program heads. For example, in Brazil UNFPA (United Nations Population Fund) sponsored a 1994 technical report on contraceptive requirements and logistics management needs that included information on donor supply of contraceptives (UNFPA 1994).

# **#** Public sector data

Collect and analyze information from both federal and state levels. Note that because the public sector buys contraceptives, receives donated contraceptives, and supplies public sector service delivery points, it is both a consumer and supplier of contraceptives. (In Brazil, for example, 43 percent of contraceptive users cited the public sector as their source of contraceptive method—DHS 1996.) From the federal ministry of health (MOH), collect information on the current and future plans for purchasing, procuring, and distributing contraceptives to public sector and social sector groups as well as information on any plans for creating a federal budget line item for contraceptive purchases. From the state MOHs, collect information on current and future plans for purchasing, procuring, and distributing contraceptives within each state and to state and municipal social sector groups. From state MOHs, also collect information on any plans for funding contraceptive purchases after any phaseout of donated products.

In addition, collect and analyze information on which methods have been most difficult to obtain and why. Further, because some programs may have stock for several years in their warehouses (or stock that is about to expire), collect information on current stocks of each contraceptive. These data may often be obtained through interviews with program mangers and from documents projecting contraceptive needs.

# NGO data

Collect and analyze information from the managers of the key family planning and reproductive health nongovernmental organizations supported by USAID on their current sources of donated contraceptives and on their plans for future purchases or donations from non-USAID sources. Collect information on NGO plans to generate income and move toward self-sufficiency as well as on how the NGOs plan to purchase contraceptives in the future. Note that, as in the public sector, nongovernmental organizations are both consumers and suppliers of contraceptives. (In Brazil, for example, 0.6 percent of contraceptive users cited NGOs as their source of contraceptive method—DHS 1996).

# **#** Commercial sector data

Collect and analyze information on the availability and price of each type of contraceptive in the commercial sector—which includes pharmaceutical manufacturers as well as importers and distributors that sell contraceptives to the pharmacies, supermarkets, private clinics, and private doctors that in turn sell to end users. (In Brazil, for example, 53.4 percent of contraceptive users cited commercial entities—pharmacies, doctors, clinics, hospitals—as their source of contraceptive method—DHS 1996.) *Table 2-1* illustrates this flow of contraceptives in the market. Major national and international pharmaceutical manufacturers of contraceptives should be contacted to determine their retail price ranges and market shares. Note that some companies may be unwilling to divulge pricing and market share data, and that an alternative source for data could be a market research company (but the cost will be high). Information can also be gathered by visiting or calling pharmacies

and large clinics to determine the range of contraceptives they sell, the brands available, and the prices.

# Table 2-1 Flow of Contraceptives in the Commercial Market Supply Methods: Condoms, Pills, Jellies, Injectables

Local Manufactu	rer! Distrik	outors¹! Retail	ers²! End l	Jser			
Foreign Manufacturer!	Importer!	Distributors <sup>1</sup> !	Retailers <sup>2</sup> !	End User			
Clinical Methods: IUDs, Implants, Fallop Ring or Clip for Female Sterilization							
Local Manufacturer!	Importer!	Distributors <sup>1</sup> !	Retailers <sup>2</sup> !	End User			
Foreign Manufacturer!	Importer!	Distributors <sup>1</sup> !	Providers <sup>3</sup> !	<b>End User</b>			

<sup>&</sup>lt;sup>1</sup>Distribution may be done by one or several independent distribution companies, depending on the size of the country; and/or be done by the manufacturer, importer, or retailer

Information on governmental regulations concerning importation and sale of contraceptives should also be collected and analyzed in order to evaluate the difficulty and cost of commercial sales. Sources include government regulatory agencies, importers, local lawyers, and national and international drug companies. In Brazil, for example, as *Table 2-2* illustrates, several organizations regulated commercial drug company operations, product and brand registration, quality control, and the importation and sale of contraceptive products.

<sup>&</sup>lt;sup>2</sup>Retailers can include pharmacies, supermarkets, kiosks, vending machines

<sup>&</sup>lt;sup>3</sup>Providers can include physicians, nurses, midwives, hospitals, HMOs, clinics

Table 2-2 Sample Regulatory Organizations and Functions Affecting Contraceptive Products in Brazil				
Organization Function				
Federal Ministry of Health	Approval of contraceptive methods			
INMETRO/Faucao Bauer	Quality control of imported contraceptives			
National Institute of Technology (INT)	Quality control of contraceptives			
Ministry of Health/National Secretary of Sanitary Vigilance Department of Technical Norms/Products Division	Authorization to function as a medical company			

# **"** Demand estimate data

Collect and analyze information on estimated demand for contraceptive methods. One way to estimate demand for a contraceptive method—that is, the number of units demanded by users per year—is based on DHS data. *Table 2-3* illustrates this calculation.

Table 2-3 Estimated Annual Market for IUDs in Brazil				
Total population of Brazil 1996	1609,000,000*			
Number of women	80,000,000			
Number of women of reproductive age (WRA)	40,000,000			
Percentage of WRA in union	70 percent			
Number of WRA in union	28,000,000			
Estimated contraceptive prevalence rate of MWRA	70.3 percent			
Number of MWRA contracepting	19,684,000			
IUD share of method mix	1.56 percent**			
Number of women using IUDs	307,070			
Estimated interval of IUD use	3 years***			
Number of IUDs demanded by users 1996	102,357			
Annual growth rate of population	1.7 percent*			
Number of IUDs demanded 1997	104,096			
Number of IUDs demanded 1998	105,866			

<sup>\*1996</sup> World Population Chart

<sup>\*\*1996</sup> DHS data

<sup>\*\*\*</sup>International factor is 3.9 years (Stover et al. 1997)

Stover et al, "Empirically Based Conversion Factors for Calculating Couple of Years of Protection." February 1997. Chapel Hill, North Carolina.

Another way to estimate demand is to collect annual sales data. Where there are no preexisting data, suppliers may be asked to share their sales data (although some companies may be unwilling to do so). In Brazil, for example, a local firm compiled and shared volume sales data for all brands of oral contraceptives (see Appendix B). Further, in some countries a study of the contraceptive market may already be available. For example, in 1994 UNFPA commissioned a technical report on contraceptive requirements and logistics management needs in Brazil (UNFPA 1994). (See Appendix C for sample market data from this report.)

#### 2.3 STRATEGY OPTIONS

In 1992, at USAID/Brazil's request, PROFIT (Promoting Financial Investments and Transfers) began identifying and evaluating options for long-term and self-sustaining maintenance of a supply of affordable contraceptives to recipients of USAID commodity donations (Brazil's social sector), and for contributing to expansion of the method mix. PROFIT, which ends in September 1997, is a six-year project funded by USAID's Office of Population to expand sustainable private sector family planning activities in developing countries and to disseminate information about its experiences. The six strategy options identified by PROFIT for Brazil, which may be appropriate in other countries depending on goals and local conditions, are as follows:

# 2.3.1 Do nothing

The option to do nothing after donated contraceptives are phased out might be chosen because resources are insufficient to fund any intervention or because the political situation requires a rapid exit. It also might be chosen because the organization's share of the total supply of contraceptives is minimal or because the public sector plans to take over the donor's supply. A further reason to choose this option might be that reasonably priced contraceptives are available through the commercial sector, and most clients can be referred to pharmacies and private providers to purchase their contraceptives.

In Brazil, this option was not chosen for several reasons. One was that many organizations receiving commodity donations served very poor women who might not use contraceptives without access to a free product. Another was that USAID could not assume that the private sector would serve either the receiving organizations or their clients who were primarily poor women. Yet another reason was that an abrupt end of commodity donations could damage the significant investment USAID had made to support and nurture family planning programs throughout Brazil.

#### 2.3.2 Negotiate with other donors to take over

This option—to negotiate with others to continue to supply donated contraceptives to recipients—might be appealing if social sector recipients are unable or unwilling to buy contraceptives from commercial sources, or if other donors are already active in the country and do not plan to phase out their donated contraceptives. Further, if other donors are supplying a significant volume of contraceptive

products, a strategy of encouraging recipients to purchase from commercial sources has little chance of success.

In addition to direct negotiations, this option includes working with recipient organizations to contact the other donors and develop proposals, which would need to be detailed and include long-term projects of contraceptive needs. Major donors of contraceptives, excluding the World Bank, include USAID (53.6 percent 1990–1994), UNFPA (24.1 percent), Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung (BMZE) and Kreditanstalt für Wiederaufbau (KfW) (8.3 percent), International Planned Parenthood Federation (IPPF) (6.2 percent), Overseas Development Administration (ODA) (3.3 percent), and others (4.5 percent) including Canadian International Development Agency (CIDA), DKT International, European Commission (EC), Japan International Cooperation Agency, Marie Stopes International (MSI), Pathfinder International, Swedish International Development Agency (SIDA), and the World Health Organization (WHO), (UNFPA 1996). *Table 2-4* presents a contraceptive donor summary that lists the contraceptives donated and the geographic focus.

Table 2-4 Contraceptive Donor Summary						
Donor	Geographic Focus					
USAID	Pills Condoms IUDs Injectables Jelly Diaphragms Foaming tablets	Worldwide				
UNFPA	Pills IUDs Condoms Jelly Diaphragms Injectables	Worldwide				
IPPF	Pills Foaming tablets	IPPF/WHR Latin America IPPF/London: Africa and Asia				
WHO/Global Program on HIV/AIDS	Diaphragms	Worldwide				
World Bank/HIV/AIDS Program	Condoms	Worldwide				

Strategy options 3 through 6 are interventions on the supply side of the contraceptive market and assume that recipient social sector organizations will purchase contraceptives. They aim to increase the availability and accessibility of contraceptives. Their success requires recipient social sector organizations to be both willing and able to pay.

To support these strategies, USAID could assist recipient organizations become more willing and able to pay. For public sector organizations, USAID could help managers of reproductive health programs convince key policymakers to allocate funds to purchase contraceptives and to put contraceptives on the list of essential drugs provided by the MOH; improve public bid regulations to ensure fairness, low price, and quality; and develop long-term projections of contraceptive needs and cost estimates so that accurate federal and state budgets can be developed to fund contraceptive purchases.

For NGOs, USAID could help managers develop specific programs and services to generate income to purchase contraceptives or improve their marketing and financial performance and management. For example, BEMFAM, the IPPF affiliate in Brazil, charges clients for services and contraceptives, operates a commercial company to sell condoms at a profit, sells family planning services to municipal governments, sells lab services, and has cut staff and improved its marketing and financial management skills. Deciding which NGOs in a country are worth assisting can be a difficult decision, however. In Brazil, for example, USAID has given some NGOs (such as BEMFAM) substantial assistance—but allowed others to make their own way.

# 2.3.3 Negotiate with commercial suppliers

This option is appealing in countries in which successful commercial companies sell contraceptives and might be willing to sell at reduced prices to low-income clients and social sector organizations. Arrangements that might be negotiated with commercial suppliers include contracts or memoranda of agreement to supply social sector organizations at concessionary prices, a social marketing project, introduction of a product into a country, and encouragement to participate in public sector commodity bids. Incentives and arguments that might be offered to commercial suppliers to influence them to enter into such arrangements include data demonstrating potential growth in sales that could more than offset price concessions, descriptions of increases in social sector capacity to purchase contraceptives as the result of USAID programs to train providers to use/prescribe methods, and funding for social marketing projects.

In Brazil, which has several contraceptive manufacturers of both condoms and pills, hundreds of commercial distributors, and thousands of retail pharmacies, PROFIT explored the possibility of involving the existing commercial sector in sales to the social sector. This option was not chosen, however, for several reasons. One was that prior to 1992 manufacturers and retailers of pharmaceutical products had to contend with strict government price controls that squeezed profit margins. When controls were eased, pill prices quickly tripled from their 1970-1991 prices (UNFPA 1994, p. 41), and manufacturers were not interested in selling their products at very low prices. Another reason was that PROFIT questioned whether an agreement with a commercial company would deliver the long-term solution USAID was seeking. A distributor could lose its supplier or switch to a supplier of a questionable product. Further, changes in a company's ownership, management, priorities, or fortunes could at any time threaten an agreement to

supply to the social sector at subsidized prices. Yet another reason was that some companies were concerned that products sold at subsidized prices would leak into the commercial market and cannibalize sales.

# 2.3.4 Negotiate with an existing NGO to sell contraceptives

This option might be chosen in countries in which there is a strong family planning NGO with high potential for sustainability. The NGO could buy contraceptives from local or international manufacturers for sale to the commercial sector at a profit but to the social sector at subsidized prices. The commercial sales would be the key to the success of this strategy because of the need to at least break even—so that there would be no drain on the NGOs' limited resources.

Advantages to this option are that the NGO would have a historic commitment to family planning and serving the disadvantaged; that sales to the private sector, if successful, would contribute to the organization's sustainability; and that an NGO with tax-exempt status might be able to import and sell commodities free of some or all local taxes. Disadvantages are that the staff of many NGOs lack business and commercial skills, which might result in higher overhead costs and an inability to compete for private sector sales; that the finances of some NGOs are precarious; and that in some countries competition among NGOs might interfere with a mandate to supply contraceptive commodities to the entire social sector.

In Brazil, because of limited public sector involvement, some NGOs served the very poor, and many had already received USAID population assistance. CPAIMC, for example, a major reproductive health care NGO in Rio de Janeiro, was a national distribution center for USAID-donated commodities until it folded in 1992. PROFIT met with most of the major family planning NGOs to discuss overall strategy and assess interest and capabilities to participate in a solution and held negotiations with BEMFAM, the largest family planning NGO in Brazil (and in which USAID was already investing significant resources to improve sustainability), and CEPARH, the leading family planning/maternal health institution in the Northeast. Although the local organizations were successful at delivering quality family planning services to poor Brazilians, they were all significantly dependent upon grants. Further, some faced declining funding and had little or no commercial expertise. Thus in Brazil, this option was not chosen because of a perceived mismatch of NGO strengths and capabilities with USAID's goal of establishing a self-sustaining source of commodities.

# 2.3.5 Develop the commercial sector

This option—developing the commercial sector in countries where donations dominate the market—makes sense where there is an emerging middle class, an established demand for contraception, and declining international assistance for family planning. The goal would be to shift wealthier clients from the social sector to the commercial sector, and at the same time target social sector products to the very poor. A coordinated effort involving donors, local government, NGOs, and the commercial sector would make such a goal easier to achieve.

In Nigeria in 1996, for example, USAID supplied approximately 85 percent of the contraceptives (in contrast to the situation in Brazil, where USAID supplied only a small fraction). In that same year, USAID sponsored a joint strategic planning exercise for all involved in the contraceptive supply in the country, including the commercial sector, government, donors, and NGOs. Opening new markets for the sale of contraceptives by the commercial pharmaceutical sector was the major goal; increasing private sector involvement in order to ensure a sustainable contraceptive supply was the plan. Decisionmakers from all stakeholder groups held a roundtable and examined ways to coordinate efforts to reduce the gap between demand for and supply of contraceptives. Recommendations were made and standing committees formed to develop an action plan to implement the recommendations. In addition, the major constraints in the national regulatory environment for contraceptive sales were identified, and the pharmaceutical manufacturers' group prepared a paper for the government on the need to eliminate tariffs, port clearance fees, and restrictions on brand-specific advertising and over-the-counter sales for some products. (USAID/Nigeria 1996)

# 2.3.6 Create a private commercial company to sell to USAID recipients

The option to create a private commercial company to sell contraceptives to recipients at a subsidized price and to commercial providers at market prices requires that the market for one or more methods presents a niche or opportunity for a new supplier. The major issue for this strategy is financial viability. Thus pursuit of this option requires rigorous financial analysis and projections. Advantages of this option include control over the mission of the company to sell to the social sector at affordable prices and the potential to become self-sustaining. Among disadvantages are the time and expense of setting up and supervising a commercial company as well as the time consumed in company management interactions.

In Brazil, PROFIT concluded that this option had the greatest likelihood of achieving USAID's goals for the phaseout of contraceptive donations. Advantages of this option were a high degree of control over the new organization's design and objectives, and dedication and responsiveness to USAID's objectives because USAID, through PROFIT (which could invest funds to expand commercial sector family planning), would initially be the source of the company's capital.

Note that USAID support and oversight of a new business venture provides both advantages and disadvantages to for-profit companies. Advantages are that USAID provides capital and technical assistance. Disadvantages are that USAID monitoring and control functions may be a burden to new companies. A new business requires rapid decisionmaking and entrepreneurial management, and these may be more difficult because of multiple stakeholders and decisionmakers. In addition, USAID also requires more auditing and reporting than most commercial companies.

# **CREATING A FOR-PROFIT COMPANY: CEPEO**

# 3.

Creating a private commercial company to sell to USAID recipients was the option selected for phaseout in Brazil. A principal reason was the potential of a for-profit company to achieve long-term sustainability. That is, sales revenue had the potential to cover all costs and expenses. However, the company also had to sell contraceptives to Brazil's social sector at affordable prices.

#### 3.1 GENERAL ASSUMPTIONS

The company—CEPEO—was designed by PROFIT from May 1992 to December 1993 in collaboration with Pathfinder International (a USAID cooperating agency) and the SOMARC III project (a social marketing project funded by USAID's Office of Population and managed by The Futures Group). CEPEO's original design was based on assumptions about product markets and suppliers made as a result of market analyses and early negotiations with manufacturers. These assumptions were that CEPEO would:

- # Sell IUDs and injectables, implement a social marketing program for pills, and act as an agent for a manufacturer of condoms and other products
- 4 Offer contraceptive products (IUDs) to Brazil's social sector at or below cost
- # Need substantial commercial sector sales (80 percent) and a diversified product line to attain sustainability
- # Focus on the Northeast region of Brazil
- # Be managed by an experienced pharmaceutical executive

CEPEO sales to the social sector would be facilitated by previous efforts to recover the costs of distributing donated products. Pathfinder International had begun in 1990 to ask donation recipients to pay a fee (which varied according to the status of the recipient but was always well below the market price) to cover administrative, transportation, and storage expenses. Two years later, Pathfinder began to offer products at higher fees to commercial sector clients. Fees were then gradually raised in preparation for the upcoming transfer of recipients and clients to CEPEO. *Table 3-1* illustrates the evolution of product fees for both markets.

CEPEO's original design assumed the same geographic focus as Pathfinder International, most of whose social sector clients (14 state institutions and NGOs) were located in the Northeast, which was also USAID's focus. Pathfinder also had 492 commercial sector clients (private doctors or clinics), of which 79 were active; most were in the state of Rio de Janeiro. Pathfinder was to assist in transferring its clients to CEPEO. Recognizing the focus on the Northeast, CEPEO was to have its headquarters in Salvador, the largest city of the region.

Table 3-1 Evolution of Product Fees							
	Fees in	Fees in 1990		Fees in 1992		Fees in 1994	
Product	Public Sector and NGO Clients	Private Physicians, Clinics, and HMOs	Public Sector and NGO Clients	Private Physicians, Clinics, and HMOs	Public Sector and NGO Clients	Private Physicians, Clinics, and HMOs	
IUD Copper T	2.30	_	4.50	8.00	8.40	18.30	
Condom	.05	_	.10	.20	.18	.60	
Spermidical Jelly	1.50	_	2.00	2.00	2.00	7.00	
Diaphragm	2.00	_	2.60	4.00	3.00	7.00	

#### 3.2 PRODUCT ASSUMPTIONS

Specific product assumptions were that CEPEO would sell IUDs and injectables, implement a social marketing program for pills, and act as an agent for a manufacturer of condoms and other products. (See Appendix E for CEPEO's original projected income statement.)

# 3.2.1 IUDs

This safe, long-term, reversible contraceptive method had very low prevalence in Brazil (0.3 percent in 1991). One reason was that IUD suppliers were few and prices to the provider were high. Organon, the only significant commercial supplier, sold its IUD to providers for \$25 in 1991. Another reason for low prevalence was that commercial suppliers made little effort to increase demand. Yet another was that physician demand for IUDs was limited because of lack of training in IUD insertion and patient management in medical schools. To address these issues, USAID and others had donated 322,000 IUDs between 1990 and 1993 (with donations accounting for an estimated 65 percent of total supply in 1991). USAID had also conducted extensive provider training.

IUDs were thus to be an important component of CEPEO's product line. PROFIT negotiated with Finishing Enterprises (FEI) to make the new company the exclusive distributor in Brazil for FEI's IUD, the Copper T 380A. CEPEO was projected to sell 80 percent of its IUDs to the commercial sector for an average margin of 157 percent and the remaining 20 percent to the social sector at or below cost.

## 3.2.2 Pills

In 1992, more than 15 brands of pills, the second most used method (after sterilization) in Brazil, were manufactured locally by several companies. The total pill market was estimated to be 70 million cycles by 1996 (UNFPA 1994). From 1990 to 1993, approximately 10.5 million cycles (representing 5 percent of total supply) were donated (UNFPA 1994—see Appendix F). As already noted, the problem with pills was not supply (except for very poor women) but incorrect use and poor compliance. Users cited side effects as a reason for discontinuation; both users and nonusers had many misconceptions and little factual knowledge (O Segundo Brasil 1992). To address this situation, SOMARC III had approached Schering and Wyeth, the market leaders (combined market share by volume of over 80 percent in 1992), about participating in a social marketing project. CEPEO would be the local entity to implement a campaign to promote compliance, correct misconceptions, and train providers and pharmacists. To finance these activities, CEPEO would earn royalties (projected to be more than \$140,000 the first year) on the sales of the socially marketed brands.

# 3.2.3 Condoms

For this method, the need was to increase demand—not only for family planning but also for combating the spread of HIV/AIDS and other sexually transmitted diseases (STDs). Brazil had the fourth highest number of cumulative AIDS cases in the world in 1990, and HIV prevalence could reach 1 million by the year 2000 (UNFPA 1994). The supply of condoms was not a problem: Brazil had four local manufacturers and several importers, more than 12 different brands were offered, and condoms were available in retail pharmacies. However, no low-priced brands were widely promoted. The market leaders (Jontex® manufactured by Johnson & Johnson and Olla® manufactured by Inal) were relatively expensive (U.S. \$.50 to U.S. \$1 per unit) (Gazetta Mercantil 1996). The total condom market was estimated to be 147 million units by 1996 (UNFPA 1994). From 1990 to 1993, more than 100 million units (representing 14 percent of total supply) were donated, and USAID made 68 percent of the donations (UNFPA 1994). In addition, in 1993 the World Bank began an AIDS/STD control project that was to include financing the procurement of 200 million condoms from 1994 to 1998 (UNFPA 1994, p. 13).

CEPEO was to include a condom product for several reasons. One was that condoms were a significant part of USAID donations. Another was the need to diversify the CEPEO product line and achieve substantial commercial sector sales. To that end PROFIT negotiated a brokerage contract with LIUSH, London Rubber's U.S. subsidiary, to introduce a line of London Rubber products (including rubber gloves, lubricants, and contraceptive jelly as well as condoms) and earn a 7 percent commission on net sales.

# 3.2.4 Injectables

Like IUDs, injectables were a highly effective and reversible alternative to female sterilization that had a very low prevalence rate in Brazil (0.8 percent in 1991). The injectable market had few suppliers, high prices, and only two products (Perlutan® manufactured by Boehringer de Angeli and Uno-Ciclo® manufactured by Bioquimico), both to be given monthly. No injectables were donated by USAID because DepoProvera®, the only U.S.-manufactured product, did not at that time have FDA approval.

Given the potential to expand the method mix and the market potential to launch a less expensive product with little competition, DepoProvera® was projected to be another important component of CEPEO's product line. DepoProvera® would also be more convenient and less expensive for consumers than competing products because it is effective for three months. PROFIT held discussions with UpJohn, DepoProvera®'s manufacturer, and discovered that the product was not yet registered with the Brazilian MOH but that UpJohn was interested in negotiations as soon as product registration was secured.

#### 3.3 ORGANIZATION STRUCTURE

USAID funding for PROFIT included funds that could be invested to expand commercial, private sector family planning around the world. These investments were generally in the form of loans or equity capital, and PROFIT established the Summa Foundation in 1992 as a legal mechanism to make the investments and hold the assets created by such investments. USAID

had the right to approve all Summa directors and control the use of all investment funds as well as any recovered capital or income from investments. To facilitate CEPEO's setup in Brazil, and establish the company's business strategies and direction, the Summa Foundation had 100 percent ownership of CEPEO, making CEPEO a wholly owned subsidiary. To simplify the implementation process and maximize USAID's ability to protect CEPEO's social objectives, the company was to be managed by a board of directors that included representatives of the PROFIT and SOMARC projects. Ownership of CEPEO was eventually to pass from the Summa Foundation to Brazilian-based entities or Brazilian equity partners after the end of the PROFIT project in 1997.

Quality management was considered the most important factor for CEPEO's success, with the ideal candidate for CEPEO's executive director assumed to be a pharmaceutical executive with experience in sales and marketing. The executive director would report directly to the board of directors.

# IMPLEMENTING AND OPERATING CEPEO

# 4.

Preoperational implementation, carried out jointly by PROFIT and SOMARC, lasted from January 1994 to March 1995 (a year longer than expected). During this time, an executive director was identified and hired, agreements were negotiated and signed with suppliers, offices were opened in Sao Paulo and Salvador, and legal documentation was obtained.

In March 1995, sales began and marketing plans were implemented. CEPEO's subsidized operations were underway. PROFIT made equity investments totaling \$700,000 over a three-year period (1995–1997 to support start-up costs, working capital needs, and initial losses. SOMARC committed \$600,000 of financial support for the same period. By 1996, CEPEO had two offices: headquarters in Salvador, Bahia (the largest city in the Northeast), and a sales office in Sao Paulo (the economic capital of Brazil). CEPEO staff included an executive director, financial/administrative manager, and sales assistant in its headquarters office in Salvador and a sales manager and office manager in the Sao Paulo office. (See the organizational chart in Appendix G.)

#### 4.1 PRODUCT LINE HISTORY

CEPEO updated the 1993 analysis of the contraceptive market in July 1995 and April 1996 as part of the company's regular cycle of business planning. In addition, USAID commissioned an external evaluation of CEPEO to assess future and potential markets in October 1996. Changes in the market, as well as opportunities created by the changes, were identified and exploited.

## 4.1.1 IUDs

CEPEO was established by 1995 as the legal importer and distributor of the Copper T 380A for Finishing Enterprises. CEPEO's sales competed primarily with Organon's Multiload CU 375 for sales to private doctors. CEPEO planned to market and distribute approximately 80 percent of its IUDs to the public sector in states that were buying contraceptives through public tendors and 20 percent to private doctors in the four states with 60 percent of all the OB/GYN practitioners in Brazil.

To expand the market in the public sector, CEPEO lobbied donor agencies to fund public sector groups at the federal and state levels to buy IUDs (instead of flooding the market with donated products); participated in federal, state, and municipal bids; and provided technical assistance in logistics to social sector groups in the Northeast. In the private sector, CEPEO

built a strong image and relationship with its market as supplier of a high-quality U.S. product, launched its own brand-name IUD—the CEPEO T—to differentiate its product from competitors, and conducted a direct mail campaign to advertise the CEPEO T and solicit direct sales from 13,000 private OB/GYN practitioners. In addition, CEPEO set up two 800 telephone lines to market its IUD, make sales, answer questions, and refer physicians for IUD training. CEPEO also sponsored IUD insertion training to the more than 255 OB/GYNs throughout the country. Further, CEPEO advertised the CEPEO T to private physicians in medical journals and made direct sales contacts with large institutional buyers such as HMOs, hospitals, and clinics.

#### 4.1.2 Pills

Manufacturers were allowed to raise prices when the federal government in Brazil liberalized price controls on pharmaceutical products in 1994. Thus in January 1995, Schering and Wyeth decided to withdraw from their tentative agreement with CEPEO to participate in a social marketing project because they were no longer willing to offer pills at below-market prices.

#### 4.1.3 Condoms

CEPEO was appointed the local agent for London Rubber in August 1994; but, in October, the general manager handling Brazil was replaced and the agreement canceled. CEPEO therefore began to source condoms locally in Brazil, which had many manufacturers and importers.

# 4.1.4 Injectables

PROFIT and CEPEO continued contacts with UpJohn concerning introduction of Depo-Provera®. The product was finally registered as a contraceptive in Brazil in December 1996. Upjohn is currently developing its marketing plan.

# 4.2 FINANCIAL AND SALES PERFORMANCE

CEPEO began to sell IUDs, its major product, in March 1995. By the end of the year, CEPEO had sold \$505,507 worth of contraceptives, with 99 percent of revenues generated by the sale of 55,832 Copper T 380As. Other products sold included condoms (142,317 in 1995), diaphragms, contraceptive jelly, and diaphragm fitting rings. During its first 18 months, CEPEO sold approximately the same number of IUDs (103,637) as USAID had donated to Brazilian operations in a four-year period (123,000), and 80 percent of CEPEO's sales were to the social sector, its target market. In addition, by December 1996 over 150 private physicians had been trained in IUD insertion through a CEPEO-sponsored training program

at six sites in five states. Further, couple years of protection (CYP) provided by CEPEO's IUD sales (360,500) exceeded the CYP provided by the local IPPF affiliate and the condom sales of a social marketing program. USAID committed approximately \$1.79 million to support CEPEO in these efforts, or approximately \$4.97 per couple year.

CEPEO, which has surpassed original revenue targets and has had lower losses than originally projected, currently expects to become profitable by the end of 1997 when USAID support (altogether totaling approximately \$2.14 million) ends (see Figure 4-1). CEPEO anticipates that by the last quarter of 1997, when technical and financial support from PROFIT and SOMARC end, it will break even, generating a small net loss of \$21,000. CEPEO is projected for 1998 to realize a profit of \$125,000. However, because CEPEO has basically sold mainly one product—the IUD—the company remains extremely vulnerable. Diversifying its product line and customer mix to become stronger commercially and financially is an important goal.

Because CEPEO was created with USAID capital, the company did experience some operational constraints because of its multiple stakeholders (PROFIT, SOMARC, USAID/Brazil, USAID/World). Communication with these stakeholders as well as the required regular reports for USAID were time consuming; consensus decisionmaking was both cumbersome and time consuming. Further, CEPEO was sometimes seen as a cooperating agency, a role that conflicted with its business needs.

#### 4.3 PHASEOUT AND FUTURE OWNERSHIP

In November 1996, as the September 1997 end of the PROFIT project approached, PROFIT presented USAID with several options regarding the future ownership of CEPEO:

- # Maintain the status quo—that is, have the Summa Foundation continue as CEPEO's owner because the Summa would survive after PROFIT ends
- Transfer the ownership of CEPEO to a local entity such as a family planning NGO
- # Sell CEPEO

By January 1997, PROFIT and USAID had resolved to sell CEPEO to a local person or organization that could maintain CEPEO's social mission and ensure its long-term financial viability. PROFIT therefore planned and implemented a fair and transparent sale process in order to identify as many potential buyers as possible, screen potential buyers according to specific criteria established by PROFIT and USAID, and award CEPEO to the buyer with the best qualifications and highest bid.

Eight buyers initially expressed interest in the CEPEO. Six withdrew from the process as they perceived they would not meet all of the criteria or as they completed their diligence. Two made bids, with CEPEO's new management successfully offering \$100,000 to buy the company in July 1997. Legal execution of the sale is currently underway.

# PHASEOUT OF DONATED CONTRACEPTIVES: LESSONS LEARNED FROM THE CASE OF CEPEO

By

# **Catherine Connor**

# STEPS IN DESIGNING FOR-PROFIT PHASEOUT COMPANIES

The PROFIT Project Promoting Financial Investments and Transfers

5.

The steps outlined in this section are based on USAID's and PROFIT's experience—that is SAID GOISTAND PEn the process of designing and operating 56EP 20-in 1990 When the phaseout strategy selected is setting up a commercial company, the first step is determining specifically the mission of the company. The mission statement should specify the company's product line and target makes. Three steps then need to be taken simultaneously: establishing the company; designing the organizational structure and staffing; and developing a business and marketing plan. Subsequent steps are identifying and planning how to exploit the market created by the USAID program; determining the USAID

funding, support, monitoring, and technical assistance required; and planning for sustainability and ownership after phaseout.

#### 5.1 DETERMINE THE MISSION OF THE COMPANY

A thorough analysis of the existing contraceptive market and potential competition (as described in section 2.2) is essential. Based on the analysis, a niche for the for-profit company in the national contraceptive market can be determined. The mission of the company will then be to sell the types of contraceptives identified (and selected) to the social sector at affordable prices and to the commercial sector at competitive prices. The mission of the for-profit company should be reassessed on a regular basis, however. The contraceptive market is certain to change over time; the mission of the company and its niche in the market may also need to change. It is important to be flexible about the mission and scope of the phaseout company as well as to be open to modifying the mission in response to changing market forces.

In Brazil, for example, CEPEO's mission evolved over time as the contraceptive market changed and as the analyses of contraceptive trends were refined. At the outset, USAID, PROFIT, and SOMARC assumed that CEPEO could become a large commercial company and sell a range of contraceptive methods throughout the country to both the social and commercial sectors. However, although CEPEO was successful in selling IUDs and a limited number of other products, it was not able to become as large as projected. Thus, by December 1996, the mission that evolved for CEPEO's niche in the Brazilian market included:

- # Operating a small commercial company and selling quality contraceptives and related health products to the public and private sectors
- Selling contraceptives to the social sector at affordable prices in order to facilitate the move from donated to purchased products and to increase access to a range of contraceptive products and choices
- # Being self-sufficient by the end of 1998—that is, being able to cover all costs and expenses for products, promotions, distribution, sales, and operations

### **5.2 ESTABLISH THE COMPANY**

After the mission is established, the company itself should be established. Crucial in this step is finding out the legal, regulatory, tax, and administrative requirements for creating a commercial company. These requirements are certain to affect the concurrent steps of designing the company's structure and staffing and developing the business and marketing plan. Fulfilling the requirements may also be much more complex, expensive, and time consuming than anticipated.

In Brazil, for example, no projections indicated that establishing CEPEO as a commercial company would take so much time or be so complicated. Factors affecting—and constraining—the process included frequent changes in the regulatory process (which interrupted functioning administrative system), delays in implementing reform of mid-and low-level bureaucratic procedures, protectionist practices that favored locally manufactured goods, slow product and company registration processes, inconsistent application of regulations and inspections, slow final rulings by the court system on company challenges regarding suspected inconsistent or incorrect application of the regulatory system, and taxes and charges applied to business transactions and sales (Ravenholt & Mobley 1997).

As a result, securing all necessary documentation from federal, state, and municipal government agencies to establish CEPEO as a limited liability corporation duly licensed in Brazil to import and commercialize ethical medical products (such as the Copper T 380A IUD) required nearly 15 months (from January 1994 to March 1995). UpJohn's registration of DepoProvera®, finally accomplished in 1997, required nearly four years. *Table 2-2* provides a sample of regulatory organizations and their functions in Brazil.

### 5.3 DESIGN ORGANIZATIONAL STRUCTURE AND STAFFING

Outlining the initial organizational structure and staffing of the company should take place concurrently with establishing the company and developing a business and marketing plan. Ownership should be clarified. Special attention should be given to the composition and powers of the company's board of directors, which should include representatives of the USAID project or cooperating agency that owns the company and monitors its operations. The role of the board is to monitor the company's commercial operations and financial performance, review and suggest company policies, and hire, supervise, and fire (if necessary) the company's executive director.

The set of skills required to run the company should be identified: selection of the executive director is crucial to success. The successful director of a small company should be a hard-working, detail-oriented, problem-solving person who is willing to perform a wide range of duties. The successful director of a for-profit phaseout company also should have:

- # Social sector orientation and commitment
- # Excellent contacts and networks among family planning programs and potential distributors
- # A broad range of management skills, including skills in financial management, strategic planning, marketing, and human resources management of a small staff
- # An entrepreneurial approach

If the company is small, all staff need entrepreneurial skills and excellent contacts with the social sector.

In Brazil, CEPEO was legally structured and incorporated as a private sector commercial company. As described in section 3.3, CEPEO was owned by the Summa Foundation, a

U.S.-based nonprofit company created by PROFIT in 1992. Note that PROFIT had the advantage of having the Summa Foundation available as a separate legal entity. More typically, USAID's cooperating agencies and projects work with local partners.

The role of CEPEO's board of directors, particularly in evaluating the performance of CEPEO's executive director, turned out to be crucial for the company's success. The board hired—and then had to dismiss—two executive directors, both of whom were business executives with experience as managers in large companies, because neither was able to adapt to the needs of a small start-up company. The third director hired by the board was a person with extensive experience with contraceptive distribution to the social sector as director of commodities for one of the USAID cooperating agencies. To date, she has successfully run the company.

#### 5.4 DEVELOP A BUSINESS AND MARKETING PLAN

Developing a business and marketing plan needs to be concurrent with establishing the company and designing the organizational structure and staffing. An effective business and marketing plan should include:

- # Company goals
- # Background on both the economic and commercial environment and the population and family planning environment of the country
- # Descriptions of the products chosen and rationales for the choices
- # Marketing plans for each product that include a description of the market, competition, sales objectives, and marketing strategy and activities
- Descriptions of staffing, legal structure, and management systems
- # A budget and financial projections

Updating the business and marketing plan annually is important. Markets, products, and situations change. Periodic updates are essential for present and future success. (See Appendix H for an outline of CEPEO's most recent business and marketing plan.) Further, detailed financial projections are essential for determining when and under what conditions the company will achieve sustainability (see section 5.7).

# 5.5 IDENTIFY AND PLAN HOW TO EXPLOIT THE MARKET CREATED BY THE USAID PROGRAM

The significant market for a for-profit phaseout company is the social sector organizations supported by USAID. The market, which includes federal, state, and municipal public sector

groups and nonprofit organizations, is created by USAID cooperating agencies that support family planning service delivery, training, and management and policy changes as well as information, education, and communication activities. In some countries, several cooperating agencies may be responsible for distributing contraceptives on behalf of USAID.

In Brazil, for example, Pathfinder International and IPPF were the major distributors of donated contraceptives. In designing and implementing CEPEO, the connection to Pathfinder International was important because Pathfinder:

- Managed a contraceptive sales organization for social sector clients as well as selected private sector clients such as private doctors, HMOs, and private clinics. This both created a client base and established a set of prices for contraceptives for CEPEO.
- Provided CEPEO with its most successful salesperson (who became CEPEO's third executive director). She had a well-established network of relationships with key social sector population organizations and was familiar with family planning, contraceptive sales, and logistics management. Most of CEPEO's sales during the first year were the direct result of her contacts with Pathfinder's former clients.
- # Prepared many of its social sector and private doctor contraceptive clients who had been receiving donated contraceptives to begin buying contraceptives from CEPEO.
- # Worked closely with the State of Bahia's Secretariat of Health to help plan purchases of contraceptives. This state program became CEPEO's largest single client.
- # Provided technical assistance in logistics management to state programs in Bahia and Ceara and to key NGOs to enable them to project their contraceptive needs accurately and distribute contraceptives more effectively. This logistics assistance was crucial in creating increased demand for contraceptives.

### 5.6 DETERMINE THE USAID FUNDING AND SUPPORT REQUIRED

The amount of funding and support that USAID must provide to set up a commercial company needs to be determined, with the amount of management and technical assistance support required depending on the skills of the staff of the company. Each USAID project also requires monitoring, with commercial company monitoring most commonly conducted through the board of directors. USAID can also monitor the progress of a company by requiring quarterly, biannual, and annual reports, which can be prepared by USAID-supported project staff, either in the country or at headquarters.

In Brazil, as of September 1997, USAID direct project funding and technical assistance amounted to approximately \$2,145 million. This included \$1,211,666 in operating funds for CEPEO, \$600,931 for technical assistance from PROFIT, and \$332,138 for technical assistance from SOMARC. The technical assistance focused on marketing, financial management, business planning and small business management, financial and sales management information systems, USAID reporting and coordination, contacts with

international pharmaceutical groups, and planning for IUD insertion training. Management support and monitoring were provided primarily by PROFIT project staff.

#### 5.7 PLAN FOR SUSTAINABILITY AND FUTURE OWNERSHIP

As a phaseout for-profit company is designed, its sustainability and future ownership should be carefully considered. A basic premise in creating a phaseout for-profit company is that it needs only start-up capital because it will eventually generate enough income to cover its costs. Questions to ask include:

- 1) When will USAID support—which includes technical assistance and management oversight as well as start-up capital—be withdrawn?
  - 2) At that time will the company be sustainable?
  - 3) What will the company's ownership be after phaseout of support?

To determine when and under what conditions income will cover costs, that is, when and under what conditions the company will achieve sustainability (and successful phaseout is possible), detailed financial projections are essential. (Preparing financial projections is fundamental in the step of developing a business and marketing plan—see section 5.4.) Unless financial projections show that the company will become sustainable before or soon after USAID financial support is projected to end, the company risks bankruptcy and closure instead of successful phaseout. Decisions about the timing of a phaseout depend on such projections because they enable assessments of the company's capacity to operate without continued donor financing and technical assistance.

In Brazil, PROFIT and SOMARC financial, technical, and management support to CEPEO, provided for approximately four years will end in September 1997 as the PROFIT project ends. However, PROFIT and SOMARC as well as a USAID evaluation team have determined that CEPEO has a good chance of becoming financially sustainable by the end of 1997. The company itself expects to attain sustainability by December 1997 (see *Table 4-1*).

Ownership of CEPEO after phaseout was determined in July 1997 through sale of the company (see section 4.3), with legal execution of the sale currently underway. Steps/tasks involved in making such a sale include:

- # Performing an external valuation of the company
- # Advertising the sale of the company
- # Evaluating potential buyers according to criteria preestablished with the donor
- Choosing a buyer and negotiating price and conditions of sale
- # Preparing and signing the sale contract and supporting documents

In Brazil, as described in section 4.3, CEPEO has achieved phaseout, and legal execution of the sale made in July 1997 is underway.

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# LINDA, WHAT DO YOU WANT TO DO WITH THIS? Is anyone available to do the research, etc.? Pat

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